

09/257,739



## UNITED STATES DEPARTMENT OF COMMERCE

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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|--------------------|-------------|-----------------------|------------------|

09/257,739 02/25/99 HIRSCHMAN

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| S | EXAMINER 3-36 |
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HM12/1003

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|           |              |
|-----------|--------------|
| ART UNIT  | PAPER NUMBER |
| BUDENS, R | 13           |

DATE MAILED:

10/03/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/22/07

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-4, 7-9 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-4, 7-9 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☒ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's request for a Continuing Prosecution Application is acknowledged. Accordingly, FINALITY of the last Office Action is withdrawn.

The Examiner acknowledges Applicant's Preliminary Amendment, Paper No. 12, filed August 22, 2001. In view of Applicant's Preliminary Amendment, the status of the claims is as follows: Claims 5-6 have been canceled; Claims 1-4 and 7-9 are currently pending before the Examiner.

The objection to the amendment of the specification under 35 U.S.C. § 132 for adding NEW MATTER is withdrawn in view of Applicant's Preliminary Amendment canceling the previous amendment (see Paper No. 12, pages 1-2).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-4 and 7-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 7 are vague and indefinite in the recitation "a." and similar language because a claim cannot have periods in the body of the claim. The only period must be at the end of the claim. Amendment of claims 1 and 7 to delete each improper occurrence of "." would obviate this rejection. Claims 1 and 7 are further vague and indefinite in the recitations of multiple method steps since the claims have multiple method steps

identified by the same single letter designation, i.e. there are two method steps designated "a," "b," etc. Therefore, it is unclear what method steps provide antecedent basis for subsequent steps referring, for example, to "step a.". Amendment of claims 1 and 7 to more clearly point out and define what is intended to be encompassed by the claimed invention would obviate this rejection. Claims 1 and 7 are further vague and indefinite in the recitation "predetermined progressively increasing amounts" or similar language throughout the claims since it is unclear what amount would be predetermined. Amendment of claims 1 and 7 to specifically recite particular amounts would obviate this rejection. Claims 1 and 7 are further vague and indefinite in the recitation "biologically acceptable pH range" since it is unclear what range is being claimed. The terminology "biologically acceptable" may have a broad range depending on what biological effect is being measured. Amendment of claims 1 and 7 to more specifically point out and define what is intended to be encompassed within the metes and bounds of the claimed invention would obviate this rejection.

Further, claims 1-4 and 7-9 remain vague and indefinite with respect to the terminology "amount of said RT-PCR product to determine the reduction of said RT-PCR product" because the claim language still does not indicate to what the RT-PCR is compared against and how the comparison, whatever it may be, relates to the down regulation of the gene. Applicant has made a *bona fide* attempt to amend the claims to overcome the rejection but has not set forth sufficient limitations in the claims to successfully overcome this rejection. It remains unclear to what standard the RT-PCR products are being compared and to what extent the comparison determines the reduction of RT-PCR product. Applicant needs to include appropriate method steps to address these issues in order to clarify the claimed method.

5 Claims 1-4 and 7-9 remain rejected under 35 U.S.C. 112, first  
paragraph, as containing subject matter which was not described in  
the specification in such a way as to enable one skilled in the art  
to which it pertains, or with which it is most nearly connected, to  
make and/or use the invention for the reasons of record set forth  
in the last Office Action. Applicant's arguments have been fully  
considered but are not deemed persuasive to overcome the rejection.  
Applicant has attempted to amend the claims to include the method  
steps of preparation of Product R. However, the claim language  
10 refers to the use of a "predetermined amount" of various reagents  
for the preparation of Product R. There is insufficient guidance  
in the specification, however, to enable the scope of the claims.  
There is insufficient guidance to allow one skilled in the art to  
determine what would constitute a "predetermined amount" of each  
15 reagent.

Further, it remains unclear in what manner the RT-PCR products  
are compared and how that comparison would determine down  
regulation of gene expression of an HIV-1 coreceptor. In other  
words, does a higher relative amount of RT-PCR correlate with  
20 increased or decreased gene expression?

Finally, the claims, as presently amended, recite multiple  
method steps with the same letter designation. Therefore, one  
skilled in the art would not be able to practice the methods of the  
claimed invention since it would be unclear from the claims what  
25 "step a" would be referred to by subsequent method steps.

In view of the above reasons, one skilled in the art would not  
be able to make and use the claimed invention with a reasonable  
expectation of success and without undue experimentation.  
Therefore, the specification fails to provide an enabling  
30 disclosure for the claimed invention.

The claimed invention appears free of the art for the following reasons. The closest relevant art are Hirschman, U.S. Patent No. 5,807,839 (A), Hirschman, U.S. Patent No. 5,807,840 (B), Bregman, U.S. Patent No. 5,902,786 (C), and most notably, Hirschman et al., *J. Investigative Medicine* 44(6):347-351, August 1996 (R).

Each of Hirschman (A), Hirschman (B) and Bregman (C) disclose Product R (Reticulose) which appears to be identical to the Product R of the instant application. Further, each of the references teach different clinical uses for Product R. However, none of the references teach the use of Product R in methods for determining down-regulation of a chemokine receptor.

Hirschman et al. (R), the most relevant prior art, discloses methods for studying the mechanisms of action of Product R (Reticulose) using H9 T lymphoma cells and HIV infection (see page 348, "Materials and Methods"). These methods appear analogous to the methods of the claimed invention except that Hirschman et al. does not specifically study the down-regulation of a chemokine receptor which is a coreceptor for HIV. The Examiner notes that in the previous May and June of 1996, just prior to publication of Hirschman et al. (R), several laboratories essentially simultaneously identified CXCR4 and CCR5, chemokine receptors on the surface of T cells, as the putative coreceptors for HIV infection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods of Hirschman et al. (R) to study the effects of Product R on chemokine receptor expression. However, it is the Examiner's opinion that, while one of ordinary skill in the art would have been motivated to undertake studies to determine if Product R had any effect on chemokine receptor expression based on the knowledge that CXCR4 and CCR5 were known coreceptors for HIV, there exists no reasonable expectation of success in such an undertaking. It is the Examiner's opinion that the prior art did

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not recognize any relationship between Product R and chemokine  
receptor down-regulation. Therefore, while one of ordinary skill  
in the art would have been motivated, such an attempt would  
constitute an "obvious to try" situation with no reasonable  
expectation of success. On this basis, the Examiner holds  
Applicant's claimed invention free of the prior art.

No claim is allowed.

Papers relating to this application may be submitted to Group  
1600 by facsimile transmission. The Fax number is (703) 308-4242.  
Please note that the faxing of such papers must conform with the  
Notice published in the Official Gazette, 1096 OG 30, (November 15,  
1989).

Any inquiry concerning this communication or earlier  
communications from the Examiner should be directed to Robert D.  
Budens at (703) 308-2960. The Examiner can normally be reached  
Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also  
be reached on alternate Fridays. If attempts to reach the Examiner  
by telephone are unsuccessful, the Examiner's supervisor, James  
Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of  
this application should be directed to the Group receptionist at  
(703) 308-0196.



Robert D. Budens  
Primary Examiner  
Art Unit 1648

rdb  
September 30, 2001